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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,778	01/14/2004	Jean-Charles Cote	12292.6	3697

7590 04/20/2005

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EXAMINER	
ROOKE, AGNES BEATA	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/756,778	COTE ET AL.	
	Examiner	Art Unit	
	Agnes B Rooke	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-15 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-15 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim 1, drawn to culture of a microorganism strain having characteristics of Bacillus thuringiensis strain, classified in class 435, subclass 832.

II. Claim 2 (a), (o), (p), 4-7, drawn to a nucleic acid molecule encoding polypeptide: SEQ ID NO:2; Claim 2(l), (o), (p), drawn to nucleic acid encoding a crystal protein having at least at least 94% identity to SEQ ID NO:2 but not SEQ ID NO:18, classified in class 536, subclass 23.1, and class 435, subclass 91.1.

III. Claim 2(b), (o), (p), 4-7, drawn to a nucleic acid molecule encoding polypeptide SEQ ID NO:8; Claim 2(m), (o), (p), drawn to nucleic acid encoding a crystal protein having at least 97% identity to SEQ ID NO:8 but not 232-723 of SEQ ID NO:18, classified in class 536, subclass 23.1, and class 435, subclass 91.1.

IV. Claim 2 (c), (o), (p), 4-7, drawn to a nucleic acid molecule encoding polypeptide SEQ ID NO:12 but not SEQ ID NO:18, classified in class 536, subclass 23.1, and class 435, subclass 91.1.

V. Claim 2 (d), (o), (p), 4-7, drawn to a nucleic acid molecule encoding polypeptide SEQ ID NO:13 but not 232 to 723 of SEQ ID NO:18, classified in class 536, subclass 23.1, and class 435, subclass 91.1.

VI. Claim 2 (e), (o), (p), 4-7, drawn to a nucleic acid molecule encoding polypeptide SEQ ID NO:14 but not SEQ ID NO:18, classified in class 536, subclass 23.1, and class 435, subclass 91.1.

VII. Claim 2 (f), (o), (p), 4-7, drawn to a nucleic acid molecule encoding polypeptide SEQ ID NO:15 but not 232 to 723 of SEQ ID NO:18, classified in class 536, subclass 23.1, and class 435, subclass 91.1.

VIII. Claim 2 (g) (o), (p), 4-7, drawn to a nucleic acid molecule encoding polypeptide crystal protein contained in Bacillus thuringiensis strain, classified in class 536, subclass 23.1, and class 435, subclass 91.1.

IX. Claim 2 (h), (o), (p), 4-7, drawn to a nucleic acid molecule encoding polypeptide SEQ ID NO:10, classified in class 536, subclass 23.1, and class 435, subclass 91.1.

X. Claim 2 (i), (o), (p), 4-7, drawn to nucleic acid of the SEQ ID NO:1, classified in class 536, subclass 23.1, and class 435, subclass 91.1.

XI. Claim 2(j), drawn to nucleic acid of the SEQ ID NO:9; Claim 2(n),(o), (p), drawn to nucleic acid encoding a crystal protein having at least 98% identity to complete sequence set forth in SEQ ID NO:9 but not 232-723 of SEQ ID NO:18, classified in class 536, subclass 23.1, and class 435, subclass 91.1.

XII. Claim 2(k), (o), (p), 4-7, drawn to nucleic acid encoding a crystal protein of the SEQ ID NO:11, classified in class 536, subclass 23.1, and class 435, subclass 91.1.

XIII. Claim 3(a), drawn to an isolated polypeptide of SEQ ID NO:2; Claim 3(e), drawn to a crystal protein with at least 94% identity to SEQ ID NO:2 but not SEQ ID NO:18, classified in class 530, subclass 350.

XIV. Claim 3(b), drawn to a protein of the SEQ ID NO:8; Claim 3(f), drawn to a crystal protein with at least 97% identity to SEQ ID NO:8 but not 232-723 of SEQ ID NO:18, classified in class 530, subclass 350.

XV Claim 3(c), drawn to crystal protein contained in the Bacillus thuringiensis strain, classified in class 530, subclass 350.

XVI. Claim 3(d), drawn to a crystal protein of SEQ ID NO:10, classified in class 530, subclass 350.

XVII. Claim 3(g), drawn to a crystal protein with at least 98% identity to SEQ ID NO:9 but not 232-723 of SEQ ID NO:18, classified in class 530, subclass 350.

XVIII. Claim 8, drawn to an antibody, classified in class 530, subclass 387.1.

XIX. Claim 9, drawn to a method of modulating active protein SEQ ID NO:8, classified in class 514, subclass 2.

XX. Claim 10, 11, 13 drawn to a method of using a polypeptide for lysing a human cell, classified in class 514, subclass 2.

XXI. Claim 12, drawn to a method of testing cytotoxity of a polypeptide, classified in class 514, subclass 2.

XXII. Claim 14, 15, drawn to a method of obtaining a cytotoxic polypeptide with a protease, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II-XXII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, Invention I claims culture of a microorganism strain, that is unrelated to the DNA sequences of Inventions II-VII, or polypeptide sequences of Inventions XIII-XVII, or methods of Inventions XIX-XXII. Therefore, the inventions are distinct.

The polypeptides of inventions XIII-XVII and polynucleotides of inventions II-XII are patently distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules. In the present invention, a polynucleotide of invention III does not necessarily encode a polypeptide of invention I. Also, the information provided by the polynucleotide of invention III can be used to make a materially different polypeptide than that of invention I. Moreover, the polypeptide of invention I can be recovered from a natural source using biochemical means, such as affinity chromatography. Therefore, the inventions are distinct.

The antibody of Invention XVIII and the polynucleotides of Inventions II-XII are patently distinct because they possess different chemical structure and have different modes of operation.

The antibody of Invention XVIII and the proteins of Inventions XIII-XVII are patently distinct entities because they possess different chemical structure and have different modes of operation.

Inventions XIII-XVII and Inventions XIX-XXII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of inventions XIII-XVII demonstrated different processes of use as set forth in the claims of inventions XIX-XXII. Therefore, the inventions are distinct.

Inventions II-XII and Inventions XIX-XXII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the polynucleotides of inventions II-XII cannot be used to practice any of the methods in inventions XIX-XXII. Therefore, the inventions are distinct.

Invention XVIII and Inventions XIX-XXII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04,

MPEP § 808.01). In the instant case, the antibody of invention XVIII cannot be used to practice any of the methods in inventions XIX-XXII. Therefore, the inventions are distinct.

Invention I and Inventions XIX-XXII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the culture of a microorganism strain of Invention I cannot be used to practice any of the methods in inventions XIX-XXII. Therefore, the inventions are distinct.

Inventions XIX-XXII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, even though the methods can use a protein, they still have different steps, different goals and different starting and ending points. Therefore, the inventions are distinct.

Since the inventions are distinct for the reasons given above, and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for the examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; Amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain

dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the Invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnes Rooke whose telephone number is 571-272-2055. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information about the PAIR system, see http://pair-direct.uspto.gov. or call 866-217-9197.

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JON WEBER
SUPERVISORY PATENT EXAMINER